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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/691,343	10/18/2000	C. Alexander Turner JR.	LEX-0070-USA	3960

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EXAMINER	
DEBERRY, REGINA M	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/691,343	TURNER ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10/20/03 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *20 October 2003*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3.☐ Applicant's reply has overcome the following rejection(s): _____.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: *4-11*.

Claim(s) withdrawn from consideration: _____.

8.☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☐ Other: _____

Continuation of 5. does NOT place the application in condition for allowance because: Claims 4-11 remain rejected under 35 USC 101, 35 USC first paragraph, enablement and 35 USC first paragraph, written description. The rejections are maintained for reasons of record.

The Examiner will summarize and address Applicants' arguments against the 35 USC 101 rejection. Applicants state that the instant sequence defines a coding single nucleotide polymorphism which are the basis for forensic analysis. Applicants state that forensic analysis does not require any information at all about the ultimate biological function of the encoded protein. Using the polymorphic marker, the skilled artisan can distinguish members of a population from one another without any additional research. Applicants maintain that because forensic biologist use polymorphic markers that the claimed sequence has a substantial and well established utility. Contrary to Applicants assertion, the instant invention lacks a substantial and well established utility. A way of identifying a population of people which carry a particular polymorphism, wherein the polymorphism itself does not cause a disease or condition (i.e. lacks a substantial utility) fails to have a "real world use".

Applicants state that evidence has been provided that conclusively establishes that those skilled in the art would believe that the claimed sequence encodes a member of the platelet derived growth factor family. Applicants resubmit literature. Applicants state that the alignments in Exhibist B, C and D indicate the extensive homolgy between the claimed sequence and a variety of members of the platelet derived growth factor family. Contrary to Applicants' assertion, evidence was provided that questioned whether the instant invention was a member of the platelet derived growth factor family. Applicants state that a lack of 100% consensus on prediction of protein function from homology information is irrelevant to the question of whether the claimed nucleic acid has a substantial and specific utility. The Examiner stated in the last Office Action, that the utility of a claimed DNA does not necessarily depend on the function of the encoded gene product, if the claimed DNA had a specific and substantial utility such as it hybridizes near a disease-associated gene or it has a gene regulating activity. The specification, however, fails to disclose that the DNA of the instant of the instant application has a substantial utility.

Applicants discuss the utility of DNA chips and cite various patents . Applicants state that expression profiling does not require a knowledge of the function of the particular nucleic acid on the chip, rather the chip indicates which DNA fragments are expressed at greater or lesser levels in two or more particular tissue types. Contrary to Applicants' assertion, the claims in the cited patents are drawn to the apparatus, the instant claims are drawn to a isolated nucleic acid.

Applicants discuss evidence of real world substantial utilities. Applicants state that the present sequences are specific markers of the human genome and such specific markers are targets for the discovery of drugs that are associated with the human disease. Applicants maintain that the instant nucleotide sequence would be ideal, novel candidates for assessing gene expression using such DNA chips. This is not found persuasive because the instant invention was never correlated with a particular disease or condition, thus it is unclear how the markers are targets for drug discovery

Applicants state that SEQ ID NO:6 can be used to map the 5 coding exons on chromosome 4. Applicants state that the fact that other nucleotide sequences could be used to map the protein coding region does not mean that the use of Applicants' sequence to map the protein coding regions of chromosome 4 is not a specific utility. Contrary to Applicants' assertion, the use of the invention is not particular to the sequence being claimed because there are other sequence which would map to the same region.

Lastly, Applicants repeat arguments regarding the requirements set forth by the Patent and Trademark Office. As was stated in the last Office Action, the current rejection is in compliance with the most currently published version of the Utility Guidelines which require that all biological inventions must have credible, specific and substantial utility. Each Patent Application is examined on its own merits, what was deemed allowable in one Patent has no bearing on this Application. The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

The Examiner will summarize and address Applicants' arguments to the 35 USC 112, first paragraph enablements rejection. Applicants incorporate their response to the rejection under 35 USC 101 in response to the rejection under 35 USC 112, first paragraph. Applicants' arguments have been fully considered but are not found to persuasive for the reasons discussed above in the maintained rejection in 35 USC 101. Applicants state that there is no requirement that all species of an invention must have all of the exact same properties. Applicants state that apparently the Examiner agrees. Applicant cites the last Office Action. This is not found persuasive. The Examiner stated specifically that there is no requirement that all species of an invention have the exact same properties, however, the rejected claims encompass fragments of NHP which do not have a property. The Examiner has not conceded that SEQ ID NO:6 is enabled. Applicants state that polynucleotide fragments comprising at least 24 contiguous bases of have the property of being unique identifiers of SEQ ID NO:6. Applicants state that the disclosed sequenes can be used to design oligonucleotides probes and primers, recombinant expression, in situ hybridization. Applicants' arguments have been considered, but not found persuasive. A fragment containing at least 24 contiguous bases could not be used in recombinant expression because a functional protein would not be made. Furthermore, fragments of polynucleotides often have less specificity than the full length sequence. In the absence of specific hybridization language, the polynucleotide fragment may correspond to any region that is highly conserved in a gene family. It allows imperfect matches and carry the risk of obtaining false signals from unrelated DNA sequences. The specification is not enabled for unrelated sequences which may cross hybridize with the instant invention. The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

The Examine will summarize and address Applicants' arguments to the 35 USC 112, first paragraph, written description rejection. Applicants state that all that is required is for the structural feature to be described. Applicants state that a claim describing a genus of nucleic acids by structure, formula, chemical name or physical properties allow one of ordinary skill in the art to distinguish the genus from other material meets the written description requiremetnt of 35 USC 112, first paragraph. Applicants maintain that polynucleotides that comprise at least 24 contiguous nucleotides from SEQ ID NO:6 are within the genus of claim 4, while those that lack te structural feature lie outside the genus. Applicants' arguments have been considered but not found persuasive. The specification discloses only a structural feature of SEQ ID NO:6. Claim 4 is drawn to at least any 24 contiguous base of nucleotide sequence in SEQ ID NO:6. These 24 contiguous bases can come from a completely different nucleotide sequence, not just SEQ ID NO:6. As was stated in the last Office Action, the claim ecompasses genes yet to be discovered. The genes could be unrelated DNA sequences, corresponding sequences from other species, mutated sequences, allelic variants, splice variants and so forth. The skilled adisan cannot envision the detailed chemical

structure of the encompassed polynucleotide and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation.. The disclosure fails to provide a representative number of species to describe the genus.The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

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